

Supplementary File: Cow's Milk Fat Obesity pRevention Trial (CoMFORT): a primary care embedded randomised controlled trial to determine the effect of cow's milk fat on child adiposity

CoMFORT Consent Form

St. Michael's
Inspired Care.
Inspiring Science.

TARGet Kids!
Cow Milk Fat Obesity pRevention Trial (CoMFORT)
Study

SickKids
THE HOSPITAL FOR
SICK CHILDREN

Why am I being asked to take part in this research?

Your child is a part of *TARGet Kids!* and this is a study for which you are eligible to participate. The *TARGet Kids!* Research group hopes to learn more about how we can provide the best care to keep children healthy as they grow and develop, including recommending the best type of milk for children.

The *TARGet Kids!* CoMFORT Study aims to find out which type of cow's milk is best for children. Whole (3.25%) and reduced fat (1%) cow's milk are widely available and consumed by many Canadian children. The purpose of this study is to find which milk recommendation lessens the risk of obesity in children and optimizes child nutrition and development.

We are inviting you to help us try and answer this question.

What do I need to do?

Children who participate in this study will be randomly assigned (have an equal chance like the flip of a coin) to receive whole (3.25%) or reduced (1%) fat milk for your child. This selection is done by the study team. Your child's doctor will let you know which cow's milk fat your child should drink based on this random assignment. We will be using information already collected as part of the *TARGet Kids!* study to help determine which milk is best, and will be conducting bi-monthly email surveys or phone calls for the study duration (until your child is 4 years old) to see how things are going.

Will I receive any compensation for participating in the study?

We will provide you with a \$25 grocery store gift card for your participation.

What would happen if I weren't in the study?

You would receive usual care from your physician.

What are the Risk and Benefits?

Since whole and reduced fat milk recommendations are currently part of usual healthcare, the risks to your child in participating are no greater than in usual care. There is no expected direct benefit to you.



CoMFORT Supplementary File

Important information

- Participation is voluntary
- You can withdraw consent at any time by talking to the *TARGet Kids!* research assistant
- Your data will be de-identified and confidentially maintained as discussed in the *TARGet Kids!* consent form
- To ensure proper study conduct, members of Sick Kids or Unity Health Toronto Research Ethics Board may review your study related data

Questions?

- If you have any questions about your participation you can contact the *TARGet Kids!* Research Manager: Dalah Mason or Principal Investigator: Jonathon Maguire @ 416-813-7654 ext. 302129.
- If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Unity Health Toronto Research Ethics Board: 416-864-6060 ext. 2557 or the Sick Kids Research Ethics Board at 416-813-8279.

By signing this research consent form, I understand and confirm that:

1. All of my questions have been answered,
2. I understand the information within this informed consent form,
3. I understand that no information about my child will be given to anyone or be published without my permission.
4. I do not give up any of my or my child's legal rights by signing this consent form,
5. I have been told that I will be given a signed and dated copy of this consent form.
6. I agree to allow the child for whom I am responsible, to take part in this study.

I agree, or consent that my child _____ may take part in this study.

Printed Name of Parent/Guardian

Parent/Guardian signature & date
(DD/MMM/YYYY)

Printed Name of person
who obtained consent

Role of person
obtaining consent

Signature & date
(DD/MMM/YYYY)

Intervention Scripts for Physicians**Reduced (1%) fat milk:**

“Your child is recommended to consume 2 cups or 500 mL of 1% cow’s milk each day. Do you have any questions about that?”

Whole (3.25%) fat milk:

“Your child is recommended to consume 2 cups or 500 mL of whole or 3.25% cow’s milk each day. Do you have any questions about that?”

Magnets for CoMFORT Study Participants



CoMFORT Email Survey Script

Your child is part of the TARGet Kids! CoMFORT study about cow's milk. We would like you to answer 3 short questions about cow's milk in your child's diet.

1. At your child's most recent well-child visit, what milk fat content recommendation did your child's physician provide?
 - a. Skim (0.1%)
 - b. 1%
 - c. 2%
 - d. Whole (3.25%)
2. What fat content of milk has your child been drinking for the past month?
 - a. Skim (0.1%)
 - b. 1%
 - c. 2%
 - d. Whole (3.25%)
3. Please select the most applicable reason for your choice to provide that fat content of cow's milk to your child:
 - a. Physician recommendation
 - b. Daycare/care provider serves it
 - c. Family/friend suggestion
 - d. Sibling/other family member drinks it
 - e. Other: _____

For children randomized to the whole milk intervention,

Please remember to provide whole (3.25%) milk cow's milk to your child.
Two cups (500 mL) is recommended each day.

For children randomized to the reduced fat milk intervention,

Please remember to provide 1% milk cow's milk to your child.
Two cups (500 mL) is recommended each day.

CoMFORT Supplementary File